K003452

DEC - 7 2000

510(k) Summary

Category:	Comments
Sponsor:	Boston Scientific Corporation 2710 Orchard Parkway San Jose, CA 95134
Correspondent:	Christina Rowe Associate, Regulatory Affairs 2710 Orchard Parkway San Jose, CA 95134
Contact Numbers:	Phone: (408) 895-3526 Fax: (408) 895-2202
Device Common Name	Steerable electrode recording catheter
Device Proprietary Name	Polaris X Steerable Diagnostic Catheter
Device Classification	Electrode recording and pacing catheter; steerable catheter
Predicate Device	EPT Diagnostic II (EPT-Dx Steerable) Catheter
Predicate Device Manufacturer(s)	EP Technologies, Inc.
Predicate Device Proprietary Name(s)	EPT Diagnostic II Catheter EPT-Dx Steerable Diagnostic Catheter
Predicate Device Classification Number	21 CFR 870.1220 and 21 CFR 870.1280
Predicate Device Classification(s)	Electrode recording and pacing catheter; steerable catheter

Date Summary Was Prepared:

November 6, 2000

Description of the Device:

The Boston Scientific Corporation / EP Technologies' Polaris X Steerable Diagnostic Catheter is a sterile, single use device used to record electrical potentials from select intracardiac locations such as the HIS bundle, the right and left ventricle, the right and left ventricle, the right and left atrium, and the coronary sinus. The Polaris X Catheter is also used to deliver pacing stimuli from an external source. The Polaris X Catheter family consists of six, 6F unidirectionally steerable diagnostic catheters built on a modified EPT-Dx

Steerable Diagnostic Catheter shaft platform with a BSC/EPT Polaris-style molded handle. Two additional ring electrodes are added to the distal shaft. The ring spacing configurations vary with each model.

Intended Use:

The Polaris X Catheter is intended for temporary use in electrophysiology studies for intracardiac stimulation (pacing) and/or recording of electrical potentials.

Technological Characteristics:

The Polaris X family of steerable diagnostic catheters are intended to be used for pacing and recording of electrograms from intracardiac locations such as the Coronary Sinus (CS). These steerable pacing and mapping catheters include 9 ring electrodes in a variety of electrode spacings, and a distal tip electrode that is 2 mm in length.

The catheter body of the Polaris X is that of the approved and marketed EPT-Dx Steerable Catheter, which is designed with a standard curve in order to easily reach the CS Ostium and which has a soft distal section in order to minimize trauma and risk of perforation.

The Polaris X Catheters use a piston-actuated unidirectional steering mechanism, contained within an ergonomically shaped cylindrical handle, that is also utilized by the currently marketed BSC/EPT Polaris catheters. A push-pull motion of the piston actuates the steering of the distal tip. The catheter is placed into point of interest positions in the heart and is guided to location by steering the distal tip area of the catheter. Tip and ring electrodes come into contact with the endocardium where electrical contact is made and pacing and recording of electrograms becomes possible. No new technology or circuitry is associated with the transmission of electrical signals to or from the endocardium -- the Polaris X Catheter relies on platinum-iridium alloy, ring electrodes (1.27 mm in length) whose circuitry is identical to standard electrode and pacing catheters. Additionally, the electrical connections made are similar to those for commercially available electrode recording and pacing catheters.

Comparison to Predicate Device:

	Predicate Device	Modified Device
510(k) Reference	K940168	Current Submission
Intended Use	Record electrical potentials from intracardiac locations	Same
Device Description	Electrode Recording Catheter; Steerable Catheter	Same
Single Use?	Yes	Same
EO Sterilized?	Yes	Same
Manufacturer	BSC/EPT	Same
Device Classification	II; 74 DRF 21 CFR 870.1220; 21 CFR 870.1280	Same

Summary of the Non-clinical Data:

Specifically, non-clinical tests adopted by and conducted for the BSC/EPT Polaris X Catheter included biocompatibility, sterility, packaging, *in vivo* performance, reliability, physical integrity, and electrical integrity testing that all passed and have shown substantial equivalence to the predicate device, the EPT-Dx Steerable Diagnostic Catheter.

Abstract of the Clinical Data:

As the non-clinical tests demonstrated the safety and effectiveness of the device, no clinical studies were conducted for the Polaris X Catheter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 7 2000

Ms. Christina L. Rowe
Associate, Regulatory Affairs
Boston Scientific Corporation
2710 Orchard Parkway
San Jose, CA 95134

Re: K003452
Trade Name: EP Technologies' Decapolor Electrode Recording and Pacing Catheter ("Polaris X" Steerable Diagnostic Catheter)
Regulatory Class: II (two)
Product Code: DRF
Dated: November 3, 2000
Received: November 7, 2000

Dear Ms. Rowe:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this

response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices
and Radiological Health

Enclosure

Intended Use Statement

510(k) Number (if known):_____

Device Name: Polaris X Catheter

Indication for Use:

The Polaris X Catheter is intended for temporary use in electrophysiology studies for intracardiac stimulation (pacing) and/or recording of electrical potentials.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K003452

Prescription Use_____ **OR** **Over-The-Counter Use**_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)